H.R. 7667, The FDA Act of 2022

The House Energy and Commerce Committee is leading a comprehensive package to reauthorize the Food and Drug Administration (FDA) User Fee Agreements.

The "FDA Act of 2022," introduced by Health Subcommittee Republican Leader Brett Guthrie (R-KY) and Health Subcommittee Chairwoman Anna G. Eshoo (D-CA), includes many provisions led by House Republicans to lower costs, spur more lifesaving innovation, secure America's supply chains, protect access to breakthrough drugs and therapies, and improve people's lives.

Lowering Drug Costs

- **H.R. 6973, the Enhanced Access to Affordable Medicines Act** by Reps. Buddy Carter (R-GA) and Angie Craig (D-MN)
  - Accelerates patient access to affordable alternatives to brand name drugs by streamlining generic drug labeling and FDA approval processes for generic drugs.
- **H.R. 7035, the Biologics Market Transparency Act** by Rep. Richard Hudson (R-NC) and Rep. Kathy Manning (D-NC)
  - Drives biopharmaceutical competition and ensures continuous access to essential medicines by requiring prompt reports of changes in availability of biologics and biosimilars.

Modernizing Drug Research & Development (R&D)

- **H.R. 2565, the FDA Modernization Act** by Reps. Vern Buchanan (R-FL), Elaine Luria (D-VA) and 33 GOP co-sponsors
  - Modernizes drug development requirements by allowing for alternative methods to animal testing in establishing drug safety and effectiveness, including cell-based assays, computer modeling, and other human-based testing methods.
- **H.R. 5566, the Finding Orphan-disease Remedies With Antifungal Research and Development (FORWARD) Act** by Reps. Kevin McCarthy (R-CA), David Schweikart (R-AZ), and Tom O'Halleran (D-AZ)
  - Supports research and drug development for therapeutics and vaccines for coccidiomycosis, commonly known as Valley Fever.
- **H.R. 4511, the FDA Advancing Collection of Transformative Science (FACTS) Act** by Reps. Michael Burgess (R-TX), Buddy Carter (R-GA), and Angie Craig (D-MN)
  - Requires FDA to issue guidance on the use of real-world data and real-world evidence to support regulatory decision making for products previously granted an emergency use authorization. Also requires a report to Congress on how frequently and under what circumstances real world evidence was accepted to support an approval of a previously authorized drug or device.

- **H.R. 6988, the Drug Manufacturing Innovation Act** by John Joyce (R-PA) and Reps. Mike Levin (D-CA)
  - Addresses rising drug costs and supply chain shortages by building upon FDA's Emerging Technology Program (ETP), which invests in the development of innovative drug manufacturing technologies.
- **H.R. 7084, the Protecting and Transforming Cyber Health Care (PATCH) Act** by Reps. Michael Burgess (R-TX) and Angie Craig (D-MN)
  - Protects consumers from potential ransomware and cyberattacks through the addition of new cybersecurity protocols for manufacturers of cyber devices, or devices that include software or that connect to the internet.
- **H.R. 7649, to direct the Secretary of Health and Human Services** to open a public docket for the submission of public comments regarding factors that should be taken into consideration when reviewing a proposed modification to an approved risk evaluation and mitigation strategy, and for other purposes, by Reps. John Joyce (R-PA), Morgan Griffith (R-VA), and Doris Matsui (D-CA)
  - Supports patient safety and access to drugs undergoing proposed modifications to approved risk, evaluation, and mitigation strategies.
- **H.R. 6948, to direct the Secretary of Health and Human Services**, acting through the Commissioner of Food and Drugs, to promulgate rules to update certain regulations relating to human cells, tissues, and cellular and tissue-based products, and for other purposes, by Reps. Dan Crenshaw (R-TX) and Michael Burgess (R-TX)
  - Addresses gaps in the generation of scientific data for cell and gene therapies by requiring FDA to convene a public workshop on best practices in the research and development of human cell-, tissue-, and cellular-based medical products.
- **H.R. 7658, the Reauthorizing the Critical Path Public-Private Partnership Program** by Reps. Debbie Lesko (R-AZ) and Tom O'Halleran (D-AZ)
  - Continues investment in public-private partnerships to advance biomedical innovation and modernize the scientific and technical tools needed to evaluate safety and effectiveness of medical products.

Protecting Patient Access

- **H.R. 6996, the Accelerating Access for Patients Act** by Rep. McMorris Rodgers (R-WA)
  - Preserves patient access to novel therapeutics approved through FDA's accelerated approval pathway while maintaining FDA's standards of safety and efficacy, supports the use of RWE in meeting post-approval studies for these drugs, and requires FDA to issue guidance on the development of novel surrogate endpoints and novel clinical trial design for post-approval studies.
- **H.R. 6888, the Helping Experts Accelerate Rare Treatments (HEART) Act** by Reps. David McKinley (R-WV) and Paul Tonko (D-NY)
  - Supports FDA's review and approval of drugs for rare and ultra-rare disease by ensuring patients and rare disease experts are informing the agency through the process of rare disease drug development.

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Securing Supply Chains

- **H.R. 7006, the Improving the Nation's Safe Pharmaceuticals and Excipients by Creating Tools for Inspecting and Overseeing Needed Supplies (INSPECTIONS) Act** by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT)
  - Enables FDA to conduct more timely and dependable domestic and foreign facility inspections, ensuring the agency has the tools needed to secure our supply chains and improve its oversight over medical product manufacturing.
- **H.R. 3927, the Manufacturing API, Drugs, and Excipients (MADE) in America Act** by Reps. Buddy Carter (R-GA) and Darren Soto (D-FL)
  - Would address US supply chain vulnerabilities by incentivizing domestic manufacturing of drugs and active pharmaceutical ingredients (APIs), facilitating the use of novel manufacturing technologies, and enhances FDA inspections.

Enhancing Program Integrity and Transparency

- **H.R. 7008, the Pre-approval Information Exchange (PIE) Act** by Rep. Brett Guthrie (R-KY)
  - Ensures patients can access safe and cutting-edge medical innovation more quickly by allowing sponsors to share certain product information with health insurers and other payors before a drug or device is approved by the FDA.
- **H.R. 6980, the Unannounced Inspections Pilot** by Reps. Richard Hudson (R-NC) and Anna Eshoo (D-CA)
  - Strengthens agency oversight over foreign medical product manufacturing through a pilot program that would conduct unannounced inspections of foreign human drug establishments and inform FDA on ensuring safety and quality of foreign operating practices.